

Art Unit: 3700

CLMPTO

05/27/04

L.F.

1. (amended) A method for audiological screening of infants and newborns employing a handheld screening device having acoustic transmitters, microphone collection means, scalp electrodes, a digital signal processor, signal transmitters, receivers and a display screen comprising:

a. generating one or more stimuli with the acoustic transmitters of the handheld screening device in each ear canal of an infant or newborn,

b. collecting any transient evoked and/or distortion product otoacoustic emission signals generated by the cochlea in each ear canal in response to the stimulus with the microphone collection means placed in the ear, and/or collecting any click or frequency stimulated brainstem response signals by placing electrodes on the scalp.

BEST AVAILABLE COPY

Art Unit: 3700

c. analyzing the response signals using binomial statistics, different artifact categories by the digital signal processor,

d. transmitting all results ("pass", "refer", "technical error") all patient related data and all measurement relevant data (~~environmental noise, probe fit, electrode impedance, signal to noise ratio, etc.~~) from the handheld screening device transmitter to a patient tracking and screening system installed on a remote computer server via transmission means, ~~such as an analog or digital phone line, cordless or wireless phone line, power line, fiber optic line, wireless LAN (blue tooth), satellite telephone line, internet phone,~~ using an external or built-in modem like interface and a predefined protocol, and

e. receiving and displaying on the handheld screening device display screen all patient related data, ~~such as name, first name, mother's name, birth date, address, in/outpatient status, patient identification, hospital identification, patient history~~ directly from a patient tracking system installed on a main server via a link to the server.

2. (original) A method according to claim 1, wherein the means to transmit the frequency mixed product electric signal from the audiologic screening device to a remote computer system comprises dial-up connections using a built-in or attached analog, digital or mobile-phone modem.

3. (amended) A method according to claim 1, wherein the means to transmit the frequency mixed product electric signal from the audiologic screening device to a remote computer system comprises LAN connections to transfer and receive data in email, ftp-, and internet or other protocols.

4. (amended) A method according to Claim 1, wherein the remote computer server receives and transmits screening and patient data via the patient tracking and screening system, which also controls the handheld screening device procedures with respect to:

- a. setting the real time clock of the screener user,
- b. providing program parameters, ~~such as service intervals, criteria, measurement methods,~~
- c. uploading software upgrades to the a device.
- d. sending messages to the screener user, including service issues and procedures.

5. (original) A method according to Claim 4, wherein the patient information includes a list of patients that are to be tested next, along with information on the patients required by the screening program, and other related information including known risk factors or general comments.

6. (original) A method according to Claim 1 wherein the audiologic screening device is programmable from the remote computer server.

7. (original) A method according to Claim 1, wherein the remote computer server receives and transmits screening and patient data

Art Unit: 3700

via the patient tracking and screening system, which also controls the handheld screening device procedures with respect to:

- a. setting the real time clock of the screener user,
- b. providing program parameters, such as service-intervals, criteria, measurement methods,
- c. uploading software upgrades to the device.
- d. sending messages to the screener user, including service-issues and procedures.

8. (original) A method according to Claim 7 wherein the service-issues are dependent on measurement results.

9. (amended) A method according to Claim 1 including combining an audiology screening database with other newborn screening data, ~~like metabolic disease screening data,~~ and using and accessing to a commonly used database on a computer or server which generates and then stores all patient and result data for different screening methods.

10. (amended) A device for audiological screening of infants and newborns comprising:

- a. means for generating one or more stimuli with acoustic transmitters in each ear canal of an infant or newborn,
- b. means for collecting any transient evoked and distortion product otoacoustic emissions generated by the cochlea in each ear canal in response to the stimulus with microphone means for generating a frequency mixed product electric signal, and brain stem responses via scalp attached electrodes,

- c. means for analyzing the response signals using binomial statistics, different artifact categories by a digital signal processor associated with the signal collecting means,

- d. means for transmitting the results (~~"pass, refer, technical error"~~); all patient related data and all measurement relevant data such as ~~environmental noise, probe-fit, electrode impedance, signal-to-noise ratio, etc.~~ directly from the screening device to a patient tracking system installed on a remote computer server, and

- e. means for receiving and displaying on the handheld screening device display all patient related data such as ~~name, first name, mother's name, birth date, address, in-outpatient status, patient identification, hospital identification, patient history, etc.~~ directly from a patient tracking system installed on a main server.

11. (original) A device for audiological screening of infants and newborns according to Claim 10, wherein the means for transmitting to the remote server is a modem in communication with the computer server.

12. (amended) A device for audiological screening of infants and newborns according to Claims 10, including a combined audiology screening database with other newborn screening data, ~~like metabolic disease screening data~~ inputted into the computer server, which generates and stores all patient and result data for different screening methods.

Art Unit: 3700

13. (original) A device for audiological screening of infants and newborns according to Claim 10, wherein the connection means for transmitting data includes:

- a. sending patient lists to the screener,
- b. updating or changing configuration information on the interconnected devices,
- c. transferring and installing new software on the screener,
- d. setting the real time clock of the screener, and/or
- e. transferring messages to the user, patient related, device related and service instructions

14. (original) A device for audiological screening of infants and newborns according to Claim 13, wherein the service-issues messages may be dependent on measurement results.

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- | | |
|--|---------------------------------------|
| <input type="checkbox"/> BLACK BORDERS | <input type="checkbox"/> |
| <input type="checkbox"/> IMAGE CUT OFF AT TOP, BOTTOM OR SIDES | <input type="checkbox"/> |
| <input type="checkbox"/> FADED TEXT OR DRAWING | <input type="checkbox"/> |
| <input type="checkbox"/> BLURRED OR ILLEGIBLE TEXT OR DRAWING | <input type="checkbox"/> |
| <input type="checkbox"/> SKEWED/SLANTED IMAGES | <input type="checkbox"/> |
| <input type="checkbox"/> COLOR OR BLACK AND WHITE PHOTOGRAPHS | <input type="checkbox"/> |
| <input type="checkbox"/> GRAY SCALE DOCUMENTS | <input type="checkbox"/> |
| <input type="checkbox"/> LINES OR MARKS ON ORIGINAL DOCUMENT | <input type="checkbox"/> |
| <input type="checkbox"/> REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY | <input type="checkbox"/> |
| <input type="checkbox"/> OTHER: _____ | <input type="checkbox"/> OTHER: _____ |

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.